IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff	:	CIVIL ACTION
v.	:	
DANIEL L. ALLGYER. Defendant	:	No. 11-02651

ORDER OF PERMANENT INJUNCTION

AND NOW, this 2nd day of February, 2012, upon consideration of Plaintiff's Motion for Summary Judgment (Doc. # 22) and Defendant's response thereto (Doc. # 24), it is hereby ordered that Plaintiff's motion is GRANTED.

It is FURTHER ORDERED that:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendant under the PHSA, 42 U.S.C. §§ 201 et seq., and the FDCA, 21 U.S.C. §§ 301-399a.

3. Defendant violates the PHSA, 42 U.S.C. § 264(a), and its implementing regulation, 21 C.F.R. § 1240.61(a), by engaging in conduct that endangers the public health and safety by distributing in interstate commerce unpasteurized milk ("raw milk") and milk products in final package form for direct human consumption.

4. Defendant violates the FDCA, 21 U.S.C. § 331(a), by introducing and delivering for introduction, and causing to be introduced and delivered for introduction, into

interstate commerce, misbranded food within the meaning of 21 U.S.C. § 343(e)(1) and (i)(1), respectively, in that the unlabeled containers in which Defendant's unpasteurized milk is delivered lack Defendant's name and place of business and the common or usual name of the product.

5. Upon entry of this Order, Defendant, any company or assumed name through which Defendant operates, and each and all his directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive notice of this Order are permanently restrained and enjoined from directly and/or indirectly doing or causing to be done any act that:

a. Violates 42 U.S.C. § 264(a), by distributing in interstate commerce unpasteurized milk and unpasteurized milk products in final package form for human consumption in violation of 21 C.F.R. § 1240.61; and

b. Violates 21 U.S.C. § 331(a), by introducing and delivering for introduction in interstate commerce food that is misbranded within the meaning of 21 U.S.C. § 343(e)(1) or (i)(1).

If the FDCA is amended or modified to allow the interstate sale of raw milk or raw milk products, advanced FDA approval is not necessary and this order is amended accordingly without the necessity for further Court action.

6. Upon entry of this Order, Defendant shall continuously display the statement:

> Daniel L. Allgyer and Rainbow Acres Farm [and/or any other entity or name by or through which Daniel L. Allgyer operates] will no longer introduce or deliver for introduction, or cause to be introduced and

> delivered for introduction, into interstate commerce, any unpasteurized milk or unpasteurized milk products. Selling or distributing Rainbow Acres Farm's unpasteurized milk and unpasteurized milk products outside the state of Pennsylvania is prohibited by federal law.

on:

a. All product labels, labeling, brochures, and other promotional materials, retail invoices, and packing slips for Defendant's unpasteurized milk and unpasteurized milk products; and

b. All websites that Defendant owns, controls, or uses, directly or indirectly, to promote or make available for purchase his unpasteurized milk and unpasteurized milk products. For each website, the statement shall be posted on the website's home page and on all web pages that make Defendant's unpasteurized milk or unpasteurized milk products available for purchase (e.g., by email, online, or telephone).

7. Defendant shall maintain complete records of the sale and distribution of all his unpasteurized milk and unpasteurized milk products that shall include, but not be limited to, the name and address of persons and entities to whom products are sold or distributed, the date of sale or distribution, the product type, and the amount or quantity. Defendant shall also maintain at least one copy of the following documentation with respect to his unpasteurized milk and unpasteurized milk products:

a. All label(s) affixed to the products;

b. All labeling affixed to shipping containers; and

c. All labeling, brochures, website pages, and other materials used to promote, describe, or refer to the products.

Upon request, FDA shall have immediate access to all of the records described in this paragraph.

8. This order does not in any way limit the FDA's ability under generally applicable federal laws and regulations to regulate, monitor, inspect, and supervise Defendant or any business operated, directly or indirectly, by Defendant. This order also does not in any way relieve Defendant of his obligations to comply with generally applicable federal laws and regulations.

9. If at any time after entry of this Order, FDA determines, based on the results of any inspection, analysis, or any other information, that Defendant is not in compliance with this Order, FDA may, as and when it deems necessary, inform Defendant, in writing, of his noncompliance and require Defendant to take immediate action, including but not limited to one or more of the following actions:

a. Cease manufacturing, processing, packing, labeling, holding, and/or distributing in interstate commerce unpasteurized milk and unpasteurized milk products intended for human consumption;

b. Submit additional reports or information to FDA;

c. Submit samples of Defendant's products for analytical testing; and/or

d. Recall at Defendant's expense any unpasteurized milk and unpasteurized milk products intended for human consumption delivered into interstate commerce.

Upon receipt of such written directive, Defendant shall immediately and fully comply with its terms. Any cessation of operations ordered by FDA as described above shall continue until:

I. Defendant receives written notification from FDA that Defendant appears to be in compliance with the terms of the written directive, the PHSA, the FDCA, and applicable regulations, and may resume operations; or

II. The written directive to cease operations has been modified or reversed by this Court.

10. Defendant shall provide notice of this Order in the following manner:

a. Within ten (10) calendar days after entry of this Order, Defendant shall: (1) provide a copy of the Order, by personal service or by certified mail, return receipt requested, to each and all of Defendant's representatives, officers, agents, employees, attorneys, successors, assigns, and all persons in active concert or participation with any of them; and (2) explain the terms of the Order to each employee.

b. Within 20 calendar days after entry of this Order, Defendant shall provide to FDA an affidavit from a person with personal knowledge of the facts therein, stating the fact and manner of Defendant's compliance with and identifying the names and positions of all persons who were notified pursuant to paragraph 12(a).

c. After entry of this Order, Defendant shall, within 5 calendar days after hiring any new employee:

I. Provide a copy of the Order, by personal service or by certified mail, return receipt requested, to such employee; and

II. Explain the terms of the Order to the employee.

11. Defendant shall notify FDA, in writing, at least thirty (30) calendar days before any change in ownership, name, or character of its business that occurs after the entry of

this Order, such as reorganization, relocation, assignment, or sale of the business that may affect compliance with this Order. Defendant shall provide a copy of this Order to any prospective successor or assignee at least thirty (30) calendar days prior to any sale or change of business, and shall furnish to FDA an affidavit of compliance with this paragraph within fifteen (15) calendar days prior to such sale or change of business.

12. If Defendant violates this Order and is found in civil or criminal contempt thereof, Defendant shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees, travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigational and analytical expenses, and any other costs or fees relating to the contempt proceedings.

13. All decisions specified in this Order shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

14. No sooner than sixty (60) months after entry of this Order, Defendant may petition this Court to dissolve this Order. If Defendant has maintained, to FDA's satisfaction, a state of continuance compliance with this Order, the FDCA, the PHSA, and all applicable regulations during the sixty (60) months preceding Defendant's petition, the United States will not oppose such petition.

15. All notifications, correspondence, and communications to FDA required by this Order shall be submitted to the Director, Philadelphia District Office, U.S. Food and Drug Administration, U.S. Custom House - 200 Chestnut Street, Philadelphia, Pennsylvania 19106.

16. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Order and for the purpose of granting such additional relief as may be necessary and appropriate.

BY THE COURT:

/s/LAWRENCE F. STENGEL
LAWRENCE F. STENGEL, J.